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AdvaMed

Advanced Medical Technology Association

May 18, 2004

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Request for Extension of Comment Period; Docket Number 2004N-0194

Dear Sir or Madam:

I am writing on behalf of the Advanced Medical technology Association (AdvaMed) to request a 60-day extension of the comment period for the proposed rule amending the combination products regulations to define "mode of action" and "primary mode of action". AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems. AdvaMed's more than 1,100 members and subsidiaries manufacture nearly 90 percent of the \$75 billion of health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world.

Our member companies manufacture a variety of medical devices that will be impacted by this proposed rule. We believe that we have critical information to contribute to the refinement of the proposed definitions and associated algorithm. However, as we are a consensus-driven organization, it takes time to advise our members and collect and organize their input. We asked that the extra time be provided so that we can provide FDA the type of high quality comments we would prefer to submit.

We appreciate your consideration in this matter. You may contact me directly at (202) 434-7267 or cjones@advamed.com.

Sincerely,

Carolyn D. Jones
Associate Vice President
Technology and Regulatory Affairs

cc: David Feigal
Beverly Rothstein

2004N-0194

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